GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3711
ANSWERED ON:24.03.2017
Compensation to the Victims of Clinical Trials
Rajendran Shri S.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the quantum of financial compensation paid by the pharmaceutical companies for clinical trial related injury or death in the country along with the parameters adopted for assessing the compensation amount during each of the last three years and the current year;

(b) the details of the provisions made by the Central Drugs Standard Control Organisation (CDSCO) in the draft guidelines on the quantum of financial compensation to be paid in case of clinical trial related injury or death of subjects;

(c) whether there have been any objections to the draft guidelines by various stakeholders; and

(d) if so, the details thereof and action taken thereon?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a) The quantum of compensation paid by the pharmaceutical companies for clinical trial related injury or death during last three years and the current year is as under:
(A) Serious Adverse Event of Injury
Year Compensation Amount
2014 Rs.18,51,647/-
2015 Rs.3,99,272/-
2016 Rs.1,28,428/-
2017 (Till 20.03.2017) Nil
Total Rs.23,79,347/-

Contdâ€¦â€¦â€¦

(B) Serious Adverse Event of death
Year Compensation Amount
2014 Rs.2,74,74,221/-
2015 Rs.1,14,36,153/-
2016 Rs.30,33,635/-
2017 (Till 20.03.2017) Nil
Total Rs.4,19,44,009/-

The above quantum has been arrived at in accordance with the norms prescribed by the Government for payment of compensation in case of serious adverse events of injury and death.
(b): The criteria for deciding quantum of financial compensation in cases of SAEs of clinical trial has already been specified by the Government and it takes into account factors such as age of the trial subject, risk factor depending on seriousness and severity of disease, presence of co-morbidity and duration of disease, congenital anomaly or birth defect, etc. or whether the SAE is reversible or not.
(c) & (d): Do not arise.
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